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Attention: 8(e) Coordinator
U. S. Environmental Protection Agency
Document Control Officer
Office of Pollution Prevention and Toxic Substances, 7407
1200 Pennsylvania Avenue, NW
Washington, DC 20460

COMPANY SANITIZED

Ladies and Gentlemen:

Subject: Results of a 24-month drinking water study in Wistar rats with Glutaraldehyde

Enclosed are results of a 24-month chronic drinking water study in Wistar rats with a test substance that was 50% glutaraldehyde (CAS 111-30-8) and 50% water. The test substance was administered to groups of 50 male and 50 female Wistar rats [(Wistar Rj:WI (SPF Han) Elevage Janvier, France] at drinking water concentrations of 0, 100, 500, and 2,000 ppm for 24 months. The study was carried out according to test guidelines 87/302/EEC, OECD No. 451 and US EPA OPPTS 870.4200.

Relevant Findings:
There was no evidence of carcinogenic activity of the test substance in either the male or female rats. At concentrations of 500 and 2,000 ppm, treatment-related, histopathological findings in the larynx and trachea were observed as shown in the following table:

Larynx	Males				Females			
Dose level (ppm)	**0**	**100**	**500**	**2000**	**0**	**100**	**500**	**2000**
No. of animals/group	50	50	50	50	50	50	50	50
Metaplasma, focal	0	0	0	0	0	0	0	5
Metaplasma, diffuse	0	0	1	18	0	0	0	25
Detritus in lumen	0	0	0	2	0	0	0	11
Trachea	**Males**				**Females**			
Dose level (ppm)	**0**	**100**	**500**	**2000**	**0**	**100**	**500**	**2000**
No. of animals/group	50	50	50	50	50	50	50	50
Metaplasma, focal	0	0	0	3	0	0	0	5
Metaplasma, diffuse	0	0	0	1	0	0	0	6
Detritus in lumen	0	0	0	0	0	0	0	3

Summary:
One male in the 500 ppm concentration and 18 males in the 2000 ppm concentration had diffuse metaplasia of the larynx. A total of thirty females had either focal or diffuse metaplasia of the larynx in the high concentration (2000 ppm). In the trachea, 4 males and 11 females had either focal or diffuse metaplasia in the 2000 ppm concentration but no tracheal metaplasia was observed in either males or females in the mid and low dose groups.

At the high concentration (2,000 ppm) 2 males and 9 females died of asphyxia that was a consequence of metaplasia in the larynx and/or trachea. Other deaths occurred but were not determined to be treatment related.

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These findings showed that long-term ingestion of a 50% glutaraldehdye/50% water solution results in metaplasia of the larynx and trachea epithelial tissues, which were localized effects not caused by systemic toxicity. Although the findings are not considered to present a substantial risk to human health or the environment because the irritation potential of glutaraldehyde is well known, reporting of results from this study under TSCA 8(e) is in accordance with EPA's policy.